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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/738,411	12/17/2003	Derrick B. McKie	SC63U-US	8908	
60723 AVON PRODU	7590 11/03/200 JCTS, INC.	8	EXAMINER		
AVON PLACE			WANG, SHENGJUN		
SUFFERN, NY	10901		ART UNIT	PAPER NUMBER	
			1617		
			NOTIFICATION DATE	DELIVERY MODE	
			11/03/2008	ELECTRONIC	

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)	
	10/738,411	MCKIE ET AL.	
Office Action Summary	Examiner	Art Unit	
	Shengjun Wang	1617	
The MAILING DATE of this communication a Period for Reply	appears on the cover sheet wit	h the correspondence address	
A SHORTENED STATUTORY PERIOD FOR REF WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory peri  - Failure to reply within the set or extended period for reply will, by stat Any reply received by the Office later than three months after the ma earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNIC 1.136(a). In no event, however, may a re od will apply and will expire SIX (6) MONT cute, cause the application to become ABA	ATION. ply be timely filed  HS from the mailing date of this communic and the communic	
Status			
1) Responsive to communication(s) filed on 17	nis action is non-final. vance except for formal matte	• •	s is
Disposition of Claims			
4) ☐ Claim(s) 1-43 is/are pending in the application 4a) Of the above claim(s) 22,26,42 and 43 is 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-21,23-25,27-41 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and	/are withdrawn from consider	ation.	
9) The specification is objected to by the Exami 10) The drawing(s) filed on is/are: a) a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct and the	ccepted or b) objected to be ne drawing(s) be held in abeyand ection is required if the drawing(s	ee. See 37 CFR 1.85(a). s) is objected to. See 37 CFR 1.12	
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority docume application from the International Bure * See the attached detailed Office action for a life.	ents have been received. ents have been received in Apriority documents have been reau (PCT Rule 17.2(a)).	oplication No received in this National Stage	
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	Paper No(s)	ummary (PTO-413) /Mail Date formal Patent Application -·	

Application/Control Number: 10/738,411 Page 2

Art Unit: 1617

## **DETAILED ACTION**

Receipt of applicant's amendments and remarks submitted July 17, 2008 is acknowledged.

As amended, claims 1-43 are pending and claims 22, 26, 42 and 43 are withdrawn as drawn to non-elected invention or species. See the election made on March 19, 2007.

## Claim Rejections 35 U.S.C. 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1-7, 23-25, 27-34, are rejected under 35 U.S.C. 103(a) as being unpatentable over Beerse et al. (US 6,294,186, IDS), in view of Duennenberger et al. (US 3,708,527, IDS), Perricone (US 6,743,433), and Wiegand et al. (US 2002/0151527, IDS).
- 3. Beerse et al. teaches a method of treating or preventing dandruff and acne comprising applying a topical composition comprising a benzoic acid derivatives, wherein the benzoic acid have hydroxyl, or halogen substituents at 2-6 positions, halogenated salicylic acids, such as 5-chlorosalicylic acid, 5-bromosalicylic acid, 5-fluorosalicylic acid, etc, are listed as preferred compounds. The amount of the benzoic acid derivative in the composition is in the range of 0.01-20%. See, particularly, the abstract; col. 3, lines 54-62; col. 6, lines 5-19; and the claims. Beerse et al. further teaches that dimethicone may be incorporated into the topical composition. See, particularly, col. 10, lines 39-48. Other active and well known cosmetics agents may also incorporated into the topical compositions includes antioxidants, such as ascorbic acid (vitamin

C) or its derivatives, thiols, such as ethane thiol, and lipoic acid. See, cols. 19-30, particularly, col. 28, lines 50-60; col. 30, lines 25-40.

- 4. Beerse et al. do not teach expressly the employment of the halogenated salicylic acids for treating the skin conditions associated with the acne.
- 5. However, Duennenberger et al. teaches that the salt of 5-chlorosalicylic acid is known to be an antimicrobial agents and useful in cosmetic composition. Wiegand et al. disclosed that sebum output, and bacterial infection is closely related to acne. Further, acne vulgaris would greatly affect skin appearance. See, particularly paragraphs 0007-0010. Perricone reveals that acne is associated with skin pore size and treatment of acne is also beneficial in reducing pore size. See, col. 3, lines 15-25.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the claimed invention was made, to employ the particular halogenated salicylic acids disclosed by Beerse et al. for treating subject with acne and/or dandruff.

A person of ordinary skill in the art would have been motivated to employ the particular halogenated salicylic acids disclosed by Beerse et al. for treating subject with acne and/or dandruff because the halogenated salicylic acid is known to be useful for treatment of acne. Furthermore, one of ordinary skill in the art would have expected the halogenated salicylic acid be useful against acne as an antimicrobial agent. It is further contended that it would have been obvious to apply the composition to skin area with acne and area without acne because the compound is known to prevent (or suppress) the development of acne. One of ordinary skill in the art would have been motivated to apply the compound to skin area with enlarged pore size (previously infected with acne) for preventing a relapse.

Furthermore, the optimization of a result effective parameter, e.g. the effective amounts of the active ingredients in a therapeutical method, is considered within the skill of the artisan. See, <u>In re Boesch and Slaney</u> (CCPA) 204 USPQ 215. Finally, incorporation of other ingredients known to be useful in the composition, such as vitamin C, lipoic acid, dimethicone, would have been within the purview of ordinary skill in the art.

Page 4

- 6. Claims 8, 9, 32 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beerse et al. (US 6,294,186, IDS), in view of Duennenberger et al. (US 3,708,527, IDS), Perricone (US 6,743,433), and Wiegand et al. (US 2002/0151527, IDS), for reasons discussed above, and in further view of O'Halloran et al. (US 6,168,798).
- 7. The prima references as a whole, do not teach expressly the employment of salicylic acid, and/or lactic acid for the treatment of acne and associated conditions.
- 8. However, O'Halloran et al. teach that  $\beta$ -hydroxyl-carboxylic acids, particularly, salicylic acid, and  $\alpha$ -hydroxyl-carboxylic acid, such as lactic acid and glycolic acid, are useful for treating acne and skin conditions associated with acne. The effective amount of salicylic acid is about 0.1% to about 15% by weight of the total composition. See, particularly, the abstract, col. 2, lines 22-30, col. 4, line 56 to col. 5, lines 27, and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to further employ salicylic acid and/or lactic acid. with the halogenated salicylic acid for treatment of acne and associated skin conditions.

A person of ordinary skill in the art would have been motivated to further to further employ salicylic acid with the halogenated salicylic acid for treatment of acne and associated skin conditions because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art. See <u>In re Kerkhoven</u>, 205 USPQ 1069.

Claims 10-21 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beerse et al. (US 6,294,186, IDS), in view of Duennenberger et al. (US 3,708,527, IDS), Perricone (US 6,743,433), and Wiegand et al. (US 2002/0151527, IDS), for reasons discussed above, and in further view of Gormley et al. (US 6,174,892), Menon et al. (WO 01/66080).

- 9. The prima references as a whole, do no teach expressly teach the employment of phytol, finasteride, and/or retinol for the treatment of acne and associated conditions.
- 10. However, Gormley et al. teach that 5α-reductase inhibitors, such as finasteride, are useful for treatment of acne. See, particularly, the abstract, and the claims. Monen et al. teaches that phytol is useful for treatment of a variety of skin conditions, including acne and associated condition. See, particularly, page 2, line 20 to page 3, line 15. Phytol is particularly useful with other well-known skin caring agents, such as retinoid, salicylic acid, 5-alpha-reductase inhibitor, such as saw palmetto and finasteride. See, particularly, pages 7-9.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to further employ  $5\alpha$ -reductase inhibitors, such as finasteride, phytol, and/or retinol, with the halogenated salicylic acid for treatment of acne and associated skin conditions.

Application/Control Number: 10/738,411

Art Unit: 1617

A person of ordinary skill in the art would have been motivated, to further employ 5α-reductase inhibitors, such as finasteride, phytol, and/or retinol, with the halogenated salicylic acid for treatment of acne and associated skin conditions because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art. See In re Kerkhoven, 205 USPQ 1069. Note the Anti-ageing active ingredients recited in claim 20 are defined to include anti-wrinkle agent, such as retinoid. See, page 1, lines 22-23, page 13, lines 10-20 of the specification.

Page 6

- 11. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beerse et al. (US 6,294,186, IDS), in view of Duennenberger et al. (US 3,708,527, IDS), Perricone (US 6,743,433), and Wiegand et al. (US 2002/0151527, IDS), for reasons discussed above, and in further view of Ptchelintsev et al. (US 5,834,513).
- 12. The prima references as a whole, do no teach expressly teach the employment of ptrioxaundecanedioic acid for the treatment of acne and associated conditions.
- 13. However, Ptchelintsev et al. teaches that oxa diacids, trioxaundecanedioic acid in particular, are known to be useful for treatment of a variety of skin conditions, including acne, blemeshed skin, hyperkeratosis. See, particularly, col. 2, line 54 to col. 3, line 3, and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to further employ oxa diacids, such as trioxaundecanedioic acid, for treatment of acne and associated skin conditions.

A person of ordinary skill in the art would have been motivated, to further employ oxa diacids, such as trioxaundecanedioic acid, for treatment of acne associated skin conditions because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art. See In re Kerkhoven, 205 USPQ 1069.

- 14. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beerse et al. (US 6,294,186, IDS), in view of Duennenberger et al. (US 3,708,527, IDS), Perricone (US 6,743,433), and Wiegand et al. (US 2002/0151527, IDS), in further view of O'Halloran et al. (US 6,168,798) for reasons discussed above, and in further view of Duffy (US 5,703,122)
- 15. The prima references as a whole, do no teach expressly teach the employment of ascorbyl-phosphoryl-cholesterol in the composition for the treatment of acne and associated conditions.
- 16. However, Duffy teaches that ascorbyl-phosphoryl-cholesterol is known to be useful in dermatological composition which contains a-hydroxyl acid, salicylic acid and/or retinoids. See, particularly, claim 1.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to further employ ascorbyl-phosphoryl-cholesterol in the composition for treatment of acne associated skin conditions.

A person of ordinary skill in the art would have been motivated, to further employ ascorbyl-phosphoryl-cholesterol in the composition for treatment of acne associated skin conditions because ascorbyl-phosphoryl-cholesterol is known to reduce the side effect of the

active ingredients herein. Further, as ascorbic acid derivatives, ascorbyl-phosphoryl-cholesterol would have been reasonably expected to be similarly useful as ascorbic acid.

## Response to the Arguments

Applicants' amendments and remarks submitted July 17, 2008 have been fully considered, but are not persuasive.

Applicants maintain that enlarged pores on skin are distinct from acne. However, it is well recognized that enlarged pores are associated with acne, as acne causes an open comedo, or blackhead which eventually yield an enlarged pore. Therefore, enlarged pores are closely related to acne development. See the remarks in the prior office action.

Further, the limitation "with the proviso that said area of skin is no affected by acne" does not distinct the claimed invention from the prior art for reasons discussed above.

Particularly, cited prior art teaches 5-halosalicylic acids are known to be useful for treatment or prevention acne, therefore, one would have been motivated to apply the halosalicylic acid to the skin of person having acne, or susceptible to have acne, regardless whether the particular skin area has acne or not.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Application/Control Number: 10/738,411 Page 9

Art Unit: 1617

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/ Primary Examiner, Art Unit 1617